

REMARKS / ARGUMENTS:

Claims 1, 15, 28, 67, 71 and 75 have been amended.

Claims 16, 17, 19, 25 and 34 – 61 have been cancelled without prejudice to their patentability, and may be reasserted in another application.

Claims 1 – 15, 18, 20 – 24, 26 – 33 and 62 – 75, are now in the case.

No new matter has been added.

Claims 1, 15, 28, 67, 71 and 75 have been amended by replacing the terms “a sulfate salt” with --- sodium sulfate ---. Support for sodium sulfate is found in the originally filed specification at least at page 9, lines 12 – 29, and in Example I.

Designation of Action as a Final Action.

The designation of the Action of October 31, 2003 as a Final Action is noted.

Rejection of claims 1 – 15, 18, 20 – 24, 26 – 33, 56, 58, 60 and 62 – 75 under 35 USC §102(a) and (b) as anticipated by, or in the alternative, under 35 USC §103(a) as obvious over U.S. Patent No. 6,013,591 to Ying *et al*

It is respectfully requested that the rejection of claims 1 – 15, 18, 20 – 24, 26 – 33, 56, 58, 60 and 62 – 75 under 35 USC §102(a) and (b) as anticipated by, or in the alternative, under 35 USC §103(a) as obvious over U.S. Patent No. 6,013,591 to Ying *et al*. be reconsidered in view of the present amendments to the claims and in view of the attached Declaration of Dr. Brian Genge and be withdrawn.

The Office has argued in the most recent Action that Ying *et al*. would appear to teach nanoparticles of tricalcium phosphate that can be used for cement, thus anticipating the instant invention. Even if not anticipating, the Office continues, overlapping ranges of amount would have been prima facie obvious to one of ordinary skill in the art.

The Office recognized, however, that Ying *et al*. does not teach the use of sodium sulfate in its compositions, and that the addition of this feature to Applicant's claims would make the present claims allowable over Ying *et al*.

In the present Response, the Applicant has amended claims 1, 15 and 28 (and, therefore, all claims that depend therefrom) to describe the feature of the presence of sodium sulfate, as suggested by the Office. Accordingly, it is maintained that claims 1 –

15, 18, 20 – 24, 26 – 33, 67, 71 and 75 are now allowable over the Ying *et al.* patent, and it is respectfully requested that these claims be allowed.

Applicant's claims 62 – 75 describe cement powders, pastes and cured cements as being capable of forming a cement that has a compressive strength of at least 65 MPa. The Applicant has argued that the highly crystalline hydroxyapatite compositions of Ying *et al.* would not have been expected to form acceptable cements, because of the low solubility and low reactivity of the materials of Ying *et al.* In response, the Office stated that, "absent any evidence experimental or otherwise, the Applicant's assertion regarding strength and the actual formation of cement is not convincing."

The Applicants have now carried out carefully controlled laboratory tests that show that crystalline hydroxyapatite compositions that are prepared by the methods taught by Ying *et al.* do not form cements having the compressive strength that is required in the present claims. Attached to this Response, and made a part thereof, is a Declaration under 37 C.F.R. §1.132 by Dr. Brian R. Genge, which describes in detail the production of crystalline hydroxyapatite by the methods described in U.S. Patent No. 6,013,591 to Ying *et al.*, and the production and testing of cements made with those materials.

In his Declaration, Dr. Genge shows that he carefully selected the conditions described by Ying *et al.* that were recommended as resulting in the best crystalline apatite material. He then made that material and used it in two tests to produce cement. He tested both cements under the same conditions as described in his present application, and found that cement produced from the Ying *et al.* material demonstrated compressive strength that was far below that obtained by his reactive TCP nanoparticles, and also, was far below the requirement of 65 MPa, which is a feature of each of claims 62 – 75.

Therefore, it has been shown that, because the Ying *et al.* patent does not teach the sodium sulfate feature that is described in claims 1 – 15, 18, 20 – 24, 26 – 33, 67, 71 and 75, that patent cannot anticipate those claims. Moreover, Ying *et al.* does not disclose any compressive strength characteristics of cements made with its materials, and, therefore, cannot anticipate or make obvious the compositions of claims 62 – 75, unless such characteristics are inherent in the Ying *et al.* material. The experimental work by Dr. Genge, that is discussed above, has shown that such compressive strength is not an inherent characteristic of cements prepared from the Ying *et al.* material.

Accordingly, it is believed that the Ying *et al.* patent, alone or in combination with any other reference, cannot anticipate or make obvious the cement powders, pastes, and cured cements of the present claims, and it is respectfully requested that this rejection be reconsidered and withdrawn.

Rejection of claims 1 – 33 under 35 USC 112, first paragraph and 35 USC 132 on the ground that the specification as originally filed does not provide support for the terms “sulfate salt” alone.

The terms “sulfate salt” have been replaced in claims 1, 15 and 28 with the terms “sodium sulfate”. The use of sodium sulfate is supported in the originally filed specification at least at page 9, lines 12 – 29, and in Example 1. Accordingly, it is maintained that the rejection on the ground of new matter should be reconsidered and withdrawn.

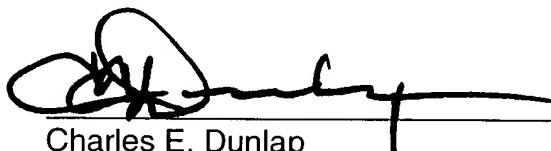
Request for reconsideration:

It is respectfully requested that the amendments that are requested above be entered into the case and that the claims be examined in view of the present amendments and be found to be allowable. If one or all of the claims are deemed to not be allowable, the Examiner is invited to call the undersigned attorney at the number given below for resolution of any remaining issues.

Respectfully requested,

NELSON MULLINS RILEY & SCARBOROUGH

DEC. 22, 2003
Date



Charles E. Dunlap
Registration No. 35,124
Keenan Building, Third Floor
1330 Lady Street
Columbia, SC 29201
Phone: (864) 250-2238
Fax: (864) 250-2394